Paper No. 43

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JOHN M. LIPARI, DAWN M. RAYMOND,
TOM REILAND, and YESHWANT D. SANZGIRI

Appeal No. 2004-0494
Application No. 09/215,831

ON BRIEF[1]

Before WINTERS, SCHEINER, and ADAMS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1, 3-5, 12, 14, 16 and 18, which are all the claims pending in the application.

Claim 1 is illustrative of the subject matter on appeal and is reproduced below:

1. A composition consisting of a fibrate dissolved in at least one monoglyceride.

The examiner relies on the following reference:

[1] Appellants waived (Paper No. 42, received April 8, 2004) their request for oral hearing, therefore we considered this appeal on Brief.

Lacy et al. (Lacy) 5,645,856 Jul. 8, 1997

GROUND OF REJECTION

Claims 1, 3-5, 12, 14, 16 and 18 stand rejected under 35 U.S.C. § 103 as being unpatentable over Lacy.

We reverse.

DISCUSSION

Appellants' claims are drawn to a composition and method of using the composition. As set forth above, claim 1 is drawn to a composition consisting of (1) a fibrate, which can be fenofibrate (see e.g., appellants' claim 3 and appellants' specification page 3, lines 28-31), and (2) at least one monoglyceride, which can be glyceryl caprylate, glyceryl oleate, or glyceryl caprylate/caprate (see e.g., appellants' claim 4 and appellants' specification page 3, lines 33-36).

According to the examiner (Answer, page 3), "Lacy discloses compositions containing fenofibrate. … Although Lacy does not teach compositions containing only monoglycerides, it is deemed obvious to one of ordinary skill in the art [at the time the invention was made] to remove any component of Lacy if that compound is deemed unnecessary…." In response appellants assert (Brief, page 3), "an essential element of the Lacy carrier

system or composition is a surfactant system…." In this regard, appellants point out (id.),

> Lacy discloses a carrier system for a hydrophobic drug which comprises a digestible oil and a surfactant comprising 1) a hydrophilic surfactant that does not substantially inhibit the lipolysis of the digestible oil, or 2) a hydrophilic surfactant which substantially inhibits the in vivo lipolysis of the digestible oil and a lipophilic surfactant capable of at least substantially reducing the inhibitory effect of the hydrophilic surfactant.

Accordingly, appellants assert (Brief, page 4), Lacy teaches away from the present invention at column 1, lines 21-23 by disclosing "the administration of a drug in oil alone is not advantageous because of the poor miscibility of the oil with the aqueous environment of the gastrointestinal tract." According to appellants (Brief, page 4), contrary to the disclosure of Lacy, their claimed composition "specifically exclude[s] a surfactant." In addition, appellants argue (id.), to the extent that the examiner relies on example 6 of Lacy, "[w]hile this example does purport to disclose a solution of fenofibrate, there are four other components, none of which is a monoglyceride as is required by each [of appellants'] claim[s]."

Appellants are correct in that Lacy discloses in the background of the specification (column 1, lines 21-23), "the administration of drug in oil alone is not advantageous because of the poor miscibility of the oil with the aqueous environment of the gastrointestinal tract." Upon review of Lacy, we find that Lacy discloses (column 3, lines 39-45), the invention "in its broadest aspect provides a carrier system for a hydrophobic drug which comprises: (a) a digestible oil, and (b) a pharmaceutically acceptable surfactant for dispersing the oil in vivo upon

administration of the carrier system, said surfactant comprising a hydrophilic surfactant component…." As we understand Lacy's disclosure, Lacy overcomes the disadvantages of using drug in oil alone by including a hydrophilic surfactant to the drug in oil composition.

However, as Lacy points out (column 3, lines 50-52), the majority of hydrophilic surfactants "will inhibit the lipolysis of the digestible oil component." Therefore, to overcome the inhibitory effect of the hydrophilic surfactant, Lacy's composition must also include a lipophilic co-surfactant. Lacy, column 3, lines 52-55. Accordingly, as we understand Lacy's disclosure, Lacy's composition includes four components, (1) a hydrophobic drug, (2) a digestible oil, (3) a hydrophilic surfactant, and (4) a lipophilic surfactant. See e.g., Lacy, column 3, lines 56-67. In contrast, appellants' claimed invention includes only (1) a hydrophobic drug (a fibrate), and (2) at least one monoglyceride. Therefore, as we understand the issue on appeal, the question is whether Lacy suggests removing two of the four components of the disclosed composition and if so, are the two remaining components (1) a fibrate and (2) at least one monoglyceride?

We note that Lacy carves out an exception to the use of digestable oils. Specifically, Lacy discloses (column 4, lines 1-5), "[i]f the lipophilic surfactant is itself a digestible oil, or can serve as the source of lipolytic products, then in a modification of the preferred carrier system a separate digestible oil component may be omitted…." In this regard, we note that Lacy discloses (column 4, lines 36-56), "examples of lipophilic surfactants which can be used for the purposes of the present invention are as follows: … 2. Mono- and/or di-glycerides of fatty

acids e.g. … Imwitor 308 (glyceryl mono-caprylate), …Capmul MCM (glyceryl caprylate/caprate), Capmul GMO (glyceryl mono-oleate), … Maisine (glyceryl mono-oleate); and Peceol (glyceryl mono-oleate)…." According to Lacy (column 6, lines 14-16), these lipophilic surfactants "are capable of serving as the digestible oil component in this invention, or serving as the source of lipolytic products.

Taking the foregoing teachings of Lacy together, the monoglycerides Imwitor 308 (glyceryl mono-caprylate), Capmul MCM (glyceryl caprylate/caprate), Capmul GMO (glyceryl mono-oleate), Maisine (glyceryl mono-oleate); and Peceol (glyceryl mono-oleate) are capable of serving as the digestible oil component in this invention, or serving as the source of lipolytic products and therefore in a modification of Lacy's preferred carrier system a separate digestible oil component may be omitted. Accordingly, such a composition would include (1) a hydrophobic drug, (2) a hydrophilic surfactant, and (3) a lipophilic surfactant. While Lacy's hydrophobic drug and lipophilic surfactant are within the scope of appellants' claimed invention, Lacy's composition includes an additional component, a hydrophilic surfactant, which is specifically excluded from appellants' claimed invention. Accordingly, this embodiment of Lacy's disclosure does not support the examiner's position.

Lacy also carves out an exception to the use of lipophilic surfactants, we note that Lacy discloses (column 8, lines 14-18), this applies to "one class of hydrophilic surfactants, namely the transesterification products of polyoxyethylene glycol with glycerol esters of capric and caprylic acids … [which

do] not substantially inhibit the in vivo lipolysis of digestible oils." According to Lacy (column 8, lines 19-23), "with this class of hydrophilic surfactants there is no necessity to include any lipophilic surfactant component at all…."

Accordingly, Lacy discloses (column 8, lines 24-30):

> [I]n a further aspect, the present invention provides a carrier system for a hydrophobic drug which comprises:
>
> (a) a digestible oil,
> (b) a transesterification product of polyoxy-ethylene glycol with glycerol esters of capric and/or caprylic acids as hydrophilic surfactant, and
> (c) optionally a lipophilic surfactant.

Lacy discloses that Labrasol (glyceryl caprylate/caprate and PEG-8 caprylate/caprate) and Softigen 767 (PEG-6 caprylic/capric glycerides) as examples of this type of hydrophilic surfactant. See Lacy, column 8, lines 31-37. Since this composition includes (1) a hydrophobic drug, (2) a digestible oil, and (3) a hydrophilic surfactant, this embodiment of Lacy's disclosure also does not support the examiner's position.

Therefore, while it may be true that Lacy suggests, under certain circumstances, that a digestible oil or a lipophilic surfactant are not necessary, and may be removed from Lacy's composition, for the foregoing reasons we find nothing in Lacy to suggest that even if these components were removed they would lead to appellants' claimed composition or the claimed method of using the composition. In this regard, we remind the examiner that "[t]he Patent Office has the initial duty of supplying the factual basis for its rejection. It may not, because it may doubt that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in its

factual basis." In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967). For the foregoing reasons, it is our opinion that the examiner has fallen "victim to the insidious effect of hindsight syndrome wherein that which only the inventor taught is used against its teacher." W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983).

Accordingly, we reverse the rejection of claims 1, 3-5, 12, 14, 16 and 18 under 35 U.S.C. § 103 as being unpatentable over Lacy.

REVERSED

Sherman D. Winters Administrative Patent Judge	)
Toni R. Scheiner Administrative Patent Judge	) BOARD OF PATENT) APPEALS AND) INTERFERENCES
Donald E. Adams Administrative Patent Judge	)

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